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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte METIN COLPAN

Appeal 2011-003576
Application 08/796,040
Technology Center 1600

Before DONALD E. ADAMS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This appeal under 35 U.S.C. § 134 involves claims 120-138 (App. Br. 5). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a process for the isolation and purification of nucleic acids from cells. Claim 120² is representative and is reproduced in the “Claims Appendix” of Appellant’s Brief (App. Br. i).

¹ Oral Hearing held January 19, 2012.

Claims 120-138 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Henco,³ Little,⁴ Dictionary,⁵ and Hames.⁶

We reverse.

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Henco suggests a method that comprises (1) lysing cells and centrifuging the lysis material to remove cellular debris; (2) adsorbing the DNA to an anion exchange column in the presence of 4 M urea; (3) washing the anion exchange column containing DNA with a buffer comprising 0.8 M NaCl; (4) desorbing the DNA from the anion exchange column with a buffer comprising 1.2 M NaCl; and (4) desalting the resulting eluate comprising DNA (Henco, col. 12, ll. 33-44; *Cf.* Ans. 4).

FF 2. Little suggests a method, wherein (1) DNA is adsorbed to diatomaceous earth in the presence of a chaotropic agent; (2) the DNA

² Claims 121-138 depend directly or indirectly from claim 120. For the purposes of this Appeal, we assume that claim 121 contains a typographical error and should properly depend from claim 120.

³ Henco et al., US 5,057,426, issued October 15, 1991.

⁴ Little, US 5,075,430, issued December 24, 1991.

⁵ International Dictionary of Medicine and Biology, Vol. 1, 522 (John Wiley & Sons, NY 1986).

⁶ Nucleic acid hybridisation a practical approach 64-65 and 235 (eds. B D Hames, et al., IRL PRESS, Washington DC, 1985).

bound diatomaceous earth is then washed; and (3) the DNA is desorbed from the diatomaceous earth with a low ionic strength buffer or water (Little, col. 2, ll. 24-31; *Cf.* Ans. 5 and 13).

FF 3. The Examiner relies on Dictionary to suggest the definition of the term “chaotropic” (Ans. 5; *see also* Little, col. 3, ll. 36-43).

FF 4. The Examiner relies on Hames to suggest “chaotropic agents” (Ans. 5; *see also* Little, col. 3, ll. 36-43).

FF 5. The Examiner finds that Henco’s cell lysis buffer comprises urea, which is a chaotropic agent (Ans. 10).

ANALYSIS

Claim 120 requires, *inter alia*, the *same* “second buffer solution” to (1) desorb nucleic acid from the anion exchange column and (2) adsorb the separated/purified nucleic acid onto the surface of a mineral support material (*see* Claim 120, steps (b) and (c); *see also* Reply Br. 4 (“step ‘c)’ uses ‘the [same] second buffer solution’ used in first-stage-desorbing step ‘b)’” (modification original)).

Henco’s method utilizes a buffer system comprising NaCl to desorb nucleic acid from an anion exchange column (FF 1). Little’s method utilizes a buffer system comprising a chaotropic agent (FF 2). Examiner provides no evidence to support a conclusion that NaCl is a chaotropic agent or a chaotropic agent within the scope of Little (*see* FF 2-4). Instead, Examiner attempts to establish a nexus between the buffer systems of Henco and Little by asserting that Henco suggests the use of a chaotropic agent, urea, as a component of a cell lysis buffer (FF 5). We are not persuaded because Henco’s cell lysis buffer is not utilized to desorb nucleic acid from Henco’s

anion exchanger (FF 1). Nevertheless, we recognize that Henco utilizes a buffer comprising urea to load nucleic acid onto an anion exchanger (FF 1). This buffer, however, is exchanged for a buffer comprising NaCl, in a wash step that precedes the step of desorbing the nucleic acid from the anion exchanger (Henco, col. 12, ll. 33-40; FF 1). Accordingly, the evidence relied upon by the Examiner fails to support a conclusion that the buffer Henco utilizes to desorb nucleic acid from an anion exchange column contains a chaotropic agent.

Therefore, without additional evidence or reasoning from Examiner, a person of ordinary skill in this art following the combination of Henco and Little, as set forth by Examiner, would be required to exchange buffers after desorbing nucleic acid from Henco's anion exchange column in order to place the desorbed nucleic acid in a buffer system that comprises a chaotropic agent before proceeding to the additional method steps suggested by Little (FF 1-2). In doing so, the requirement that Appellant's second buffer is used in both steps b) and c), discussed above, are not met. Dictionary and Hames fail to make up for the evidentiary gap in Examiner's reasoning.

In sum, Examiner failed to establish an evidentiary basis in the art relied upon to support a prima facie case of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness. The rejection of claims 120-138 under 35 U.S.C. § 103(a) as unpatentable over the combination of Henco, Little, Dictionary, and Hames is reversed.

REVERSED

cdc